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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
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EXAMINER	
QUAN, ELIZABETH S	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/742,803	MCLUEN ET AL.	
	Examiner	Art Unit	
	Elizabeth Quan	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-30 and 35-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-30 and 35-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03092004,01202004*

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 27-30 and 35-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Neither the specification nor drawings disclose what a bored interior with consistent dimension is. The confusing term is "consistent dimension". What is "consistent dimension"? If consistent dimension is referring to constant cross-section along a length, such that the bored interior has the same cross-section along any point of its length and the same cross-section along any point of its width, then fig. 6 shows a bored interior with inconsistent dimension since the cross-section at different points of its vertical length is not the same. It is unclear what structure or configuration provides for a vial with consistent dimension and maintains consistent flow, which has not been adequately described as what constitutes "consistent" flow. There appears to be no support for maintaining a consistent flow through the bored interior during a flushing procedure by **only** forming a pressure differential to expel material from the vial, which was added in the preliminary amendment. The instant specification discloses that reagent is purged from the vial due to a sufficient pressure differential, but it does not disclose that it is purged by **only** forming a pressure differential. Potentially, a substantial

amount of the reagent is purged, but some make leak through the frit and solid support by gravity or capillary action. There appears to be no support for "...wherein the solid support and material formed on the solid support is retained above the frit, within the vial, during a flushing procedure, thereby forming reactionary material..." The specification discloses a reagent is placed in contact with the solid support to cause sequenced growth, and flushing purges the reagent. The specification does not disclose flushing as forming reactionary material. It appears flushing provides the opportunity for adding a different reagent to form the sequenced growth

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 27-30 and 35-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 27-30 and 35-44, it is unclear what is characterized by "consistent dimension" and "consistent flow". Additionally, the term "configured" is confusing since it is unclear whether the structure following the term thereafter is part of the claim. The claim recites, "[a] vial has a bored interior...configured to hold a frit...and maintain a consistent flow...", but it does not appear to necessarily mean that the vial is holding a frit and maintaining a consistent flow. It is also unclear what structure "configured" relates to. For example, "...configured to hold a frit...and maintain a consistent flow..." raises the question of exactly what structure provides for this function. Additionally, it is unclear whether the recitation "...wherein the solid support and material formed on the solid support is retained above the frit, within the vial, during a flushing procedure, thereby forming reactionary material" refers to the

solid support and the material formed thereon is retained on the frit to form reactionary material or the flushing procedure forms reactionary material. In either case, it does not make sense since the material formed thereon is not disclosed as subsequently forming a reactionary material and the flushing operation does not form reactionary material. Additionally, claims 27 and 35 do not positively recite "a frit" by reciting "configured to hold a frit", such that the claim omits the essential element "frit", which is required in order for dependent clams 39, 40, 43, and 44 to make sense since they are directed to a solid support retained within the vial above the frit. These dependent claims 39, 40, 43, and 44 may be considered as failure to limit parent claims 27 and 35 since they are directed to limiting a limitation that is not positively recited.

Claim Rejections - 35 USC § 102

6 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

7. Claims 27-30 and 35-44 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,368,823 to McGraw et al.

McGraw et al. disclose vials (11) each with a top opening (13), bored interior holding a frit (9) that retains a solid support (100) of controlled pore glass (CPG) appropriated derivatized with a protected nucleoside (A, C, T, or G) on the frit, and bottom opening (14) (figs. 2, 4-6; col. 3, lines 33-48; col. 5, lines 49-66). Each vial has an exterior dimension that fits within a receiving hole of a cartridge (16) for a pressure-tight seal between each vial and cartridge (figs. 2, 4-6; col. 4, lines 33-37; col. 5, lines 44-55).

When reagents are added to the vials, each reagent will be sustained by the porous material to saturate and interact with the derivatized support for a desired incubation period until drawn through the frit by application of a pressure differential to the inlet and outlet ends of the vials (col. 4, lines 9-16; col. 5, lines 49-66; col. 6, line 58-col. 23). A dispensing system (18,20,33) supplies reagent into the top opening of the vial (figs. 2-5; col. 3, line 45-col. 5, line 6; col. 7, lines 5-23; col. 21, lines 10-17). The synthesis of oligonucleotide sequence is accomplished by: a deblocking step in which a deblocking reagents are added to remove the 5'blocking elements from the derviatized nucleosides attached to the supports to enable the nucleosides to be reactive to coupling reagents followed by flushing the supply line and washing the vials with deblocking reagents, coupling step by coupling all supports requiring nucleotide reagent "A" and flushing and priming the supply line thereafter, coupling all supports requiring nucleotide reagent "C" and flushing and priming the supply line thereafter, coupling all supports requiring nucleotide reagent "G" and flushing and priming the supply line thereafter, and coupling all supports requiring nucleotide reagent "T" and flushing and priming the supply line thereafter followed by an incubation period, removal of reagents from the vials by vacuum, and washing the coupled supports to remove unreacted reagents, oxidizing step in which the coupled supports are oxidized; washing step in which the supports are washed; capping step in which a blocking compound is added to cap any nascent olignucleotides that failed to couple; and washing step in which the coupled supports are washed. The latter steps are repeated with the addition of reagents to provide the next base in the sequence (figs. 8-10; tables 1-4; col. 6, line 58-col. 11, line 68).

Applicant has not provided a definition or description of what constitutes a bored interior with consistent dimension. For examining purposes, any vial or bored interior inherently has consistent dimensions. Furthermore, McGraw et al. disclose a vial similar in configuration to that of the instant invention shown in fig 6 in which the bore is tapered inwardly to facilitate flow. It appears that in the vial of McGraw et al. that the cross-section along any point of the vial's length is the same and the cross-section along any point of the vial's width is the same, such that the vial has consistent dimension.

Applicant has not provided a definition or description of what constitutes consistent flow. For examining purposes, flushing of the bored interior by only a pressure differential provides consistent flow during the flushing procedure. McGraw et al. disclose that reagents remain above the frit to interact with the solid support until a vacuum is applied to create a pressure differential to the inlet and outlet ends of the vial to remove the reagents from the vials.

8 Claims 27-30 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,874,691 to Chandler.

Chandler discloses vials each with a top opening, bored interior holding a frit, and bottom opening (figs. 4 and 5). The vial holds reagents or samples, which are waiting to be drawn through the frit (figs. 4 and 5; col. 4, line 55-col. 5, line 12). Gravity will be insufficient to withdraw the sample and/or reagent through the frit (figs. 4 and 5; col. 4, line 55-col. 5, line 12). Liquid will flow through the frit with application of a pressure differential—vacuum (figs. 4 and 5; col. 4, line 55-col. 5, line 12). Any positions or holes without a vial will be stoppered, and the vacuum is turned on to simultaneously impregnate the frit with the sample and/or reagent (figs. 4 and 5; col. 4, line 55-col. 5, line 12). The luer nipples at the bottom portion of the vials fit within

a receiving hole of a cartridge for a pressure-tight seal between the nipple and cartridge (figs. 4 and 5; col. 4, line 55-col. 6, line 21).

Applicant has not provided a definition or description of what constitutes a bored interior with consistent dimension. For examining purposes, any vial or bored interior inherently has consistent dimensions. Furthermore, Chandler discloses a vial similar in configuration to that of the instant invention shown in fig. 6 in which the bore is tapered inwardly to facilitate flow. It appears that in the vial of Chandler that the cross-section along any point of the vial's length is the same and the cross-section along any point of the vial's width is the same, such that the vial has consistent dimension.

Applicant has not provided a definition or description of what constitutes consistent flow. For examining purposes, flushing of the bored interior by only a pressure differential provides consistent flow during the flushing procedure. Chandler discloses that reagents remain above the frit until a vacuum is applied to remove the reagents from the vials.

Double Patenting

9. Claims 27-30 and 35-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36, 42, 44, 46, 47, 51, 66, and 70 of U.S. Patent No. 6,270,730. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain all structural limitations including bored interior and frit. As for the controlled pore glass beads, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the beads to perform certain assays such as oligonucleotide sequence ~~[illegible]~~ analysis.

Response to Arguments

10. Applicant's arguments filed 3/18/2004 have been fully considered but they are not persuasive.

11. Applicant refers to several passages of the specification to show that there is support for maintaining consistent flow through the bored interior during a flushing procedure by **only** forming a pressure differential to expel material from the vial, which was added to the original claims by way of a preliminary amendment. These passages disclose that solution is purged by a sufficient pressure differential, but they do not limit flushing by **only** forming a pressure differential. The key word is "only". The passages do not disclose purging by a single force—pressure differential. Most of the solution may be purged from the vial by a pressure differential, but it does not prevent gravity to incur slight purging or leakage from the vial. Therefore, Examiner maintains the 112, first paragraph rejection.

12. Applicant argues that Chandler does not teach that material is retained above the membrane during and after the vacuum is applied. Applicant argues that Chandler also does not teach that vials are held by a pressure-tight seal within a receiving hole of a cartridge. Examiner notes that Applicant does not recite that material is retained above the membrane during and after vacuum is applied in the claims. The claim recites "...a frit for retaining material within the vial above the frit and maintain a consistent flow through the bored interior during a flushing procedure by only forming a pressure differential to expel material from the vial." Chandler discloses that sample and/or reagent material is retained within the vial above the frit until a vacuum is applied, such that flushing occurs by only forming a pressure differential to expel material from the vial. Applicant has not provided a definition of a "pressure-tight seal".

Examiner maintains that Chandler teaches the vials are held by pressure-tight seal within a receiving hole of a cartridge since sample and/or reagent flows when vacuum is initiated. If there were no pressure-tight seal between the vial and receiving hole of the cartridge, application of a vacuum would not be able to initiate flow through the frit since the vacuum would be sucking air through the openings between the vial and receiving hole of a cartridge. Furthermore, if any receiving holes were unfilled with vials, Chandler discloses stoppering the holes and then turning on the vacuum. Chandler may not explicitly use the terms "pressure-tight seal" to describe the seal between the vial and receiving hole of the cartridge but the apparatus requires this "pressure-tight seal" in order for the vacuum to be effective. If Applicant were claiming a perfect seal between the vial and receiving hole of the cartridge, Examiner notes that this is an unrealistic limitation since every seal is not perfect since there will be microscopic openings in the seal between two objects.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (571) 272-1261. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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